

*Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.*

# Medical Countermeasure Systems (MCS)

## *Command Overview Briefing*

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**MCS**  
MEDICAL COUNTERMEASURE SYSTEMS

# WHO WE ARE



**MCS**  
MEDICAL COUNTERMEASURE SYSTEMS



# Medical Countermeasure Systems (MCS)

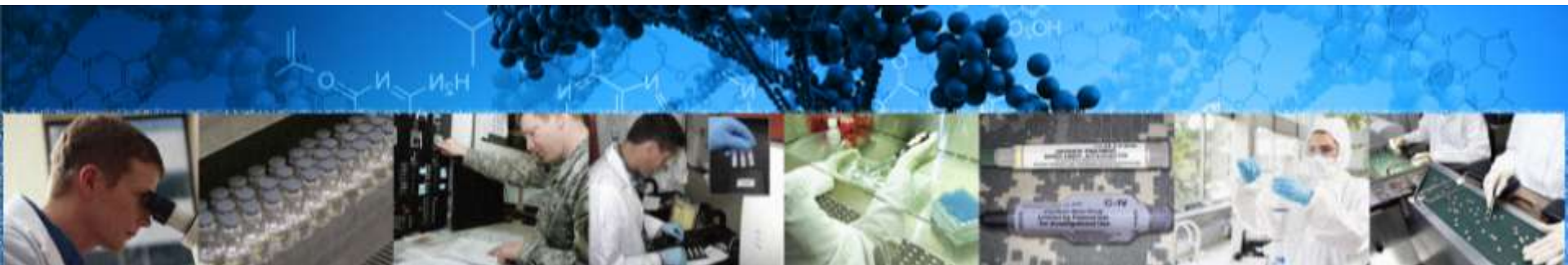


## ■ VISION

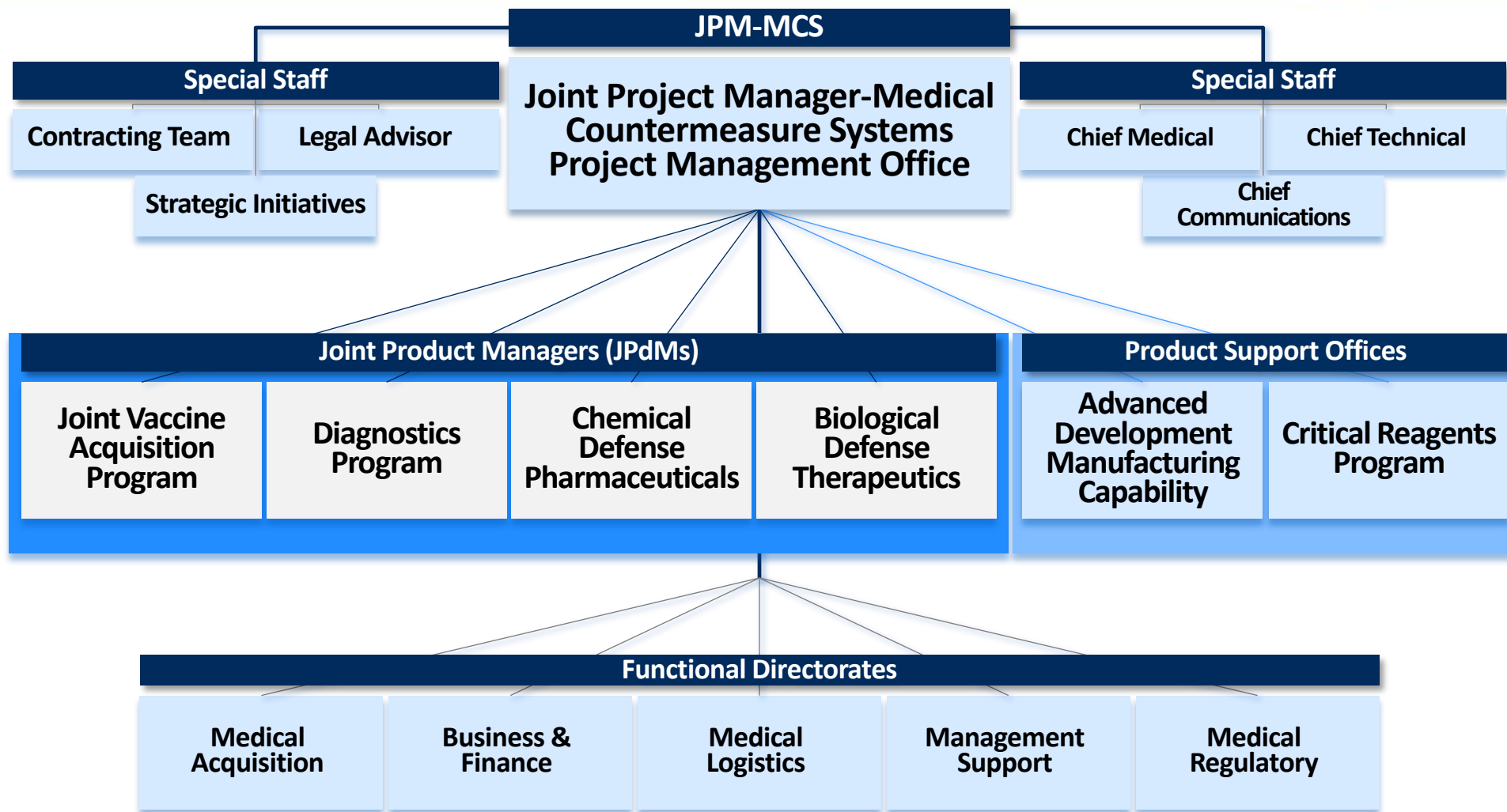
A U.S. military force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide

## ■ MISSION

To provide U.S. military forces and the nation safe, effective, and innovative medical solutions to counter CBRN threats



# MCS Organizational Structure



# Joint Product Managers



■ **JVAP**  
Joint Vaccine  
Acquisition  
Program

Develop, produce, and stockpile FDA-licensed biological defense **vaccines**



■ **DX**  
Diagnostics

Develop and field FDA-cleared **diagnostic medical devices** intended for early diagnosis of exposure to CBRN agents



■ **CDP**  
Chemical  
Defense  
Pharmaceuticals

Develop and produce FDA-approved **therapeutic & prophylactic solutions** to counter traditional and emerging chemical, radiological, and nuclear threats



■ **BDTX**  
Biological  
Defense  
Therapeutics

Develop and produce FDA-approved **therapeutic solutions** to counter traditional, emerging and engineered biological threats



# Product Support Offices



■ **ADMC**  
Advanced  
Development  
Manufacturing  
Capability

Provide DoD **focused manufacturing** facility to rapidly produce biologics against CBRN threats



■ **CRP**  
Critical  
Reagents  
Program

Serve as the principal resource of high quality, validated, and standardized **biological detection assays and reagents**



# Advanced Development Core Competencies



2086 YEARS EXPERIENCE

## ACQUISITION

### PROGRAM MANAGEMENT

20% (411 Years)

- DoD 5000.02
- Risk Management
- Life Cycle Management

## FINANCE

9% (201 Years)

- PPBES
- EVMS
- Cost Analysis

## LIFE CYCLE LOGISTICS

8% (173 Years)

- Integrated Logistics Support
- Supply Chain Management
- Property Management
- Cold Chain Management

## MANAGEMENT SUPPORT

14% (287 Years)

- Administration
- Graphics
- Human Resources
- IMIT
- Security



## REGULATORY

11% (224 Years)

- FDA
- Clinical Trials
- Animal Rule
- Biosurety
- PESHE

## SCIENCE & TECHNOLOGY

32% (660 Years)

- Pharmaceutical Development
- Assay Development
- Manufacturing
- Clinical Trials (Test & Evaluation)

## SPECIAL SERVICES

6% (131 Years)

- Communications
- Contracting
- Legal
- Medical & Technical Initiatives
- Strategic Initiatives



# WHAT WE DO



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# Products in the Pipeline

LEGEND: PREVENTION DIAGNOSTICS THERAPEUTICS

DoD FDA ★ = FDA Cleared

CAPABILITY		PRODUCT		MDD	MSA	MSB		MSC (LRIP)			
			IND	PHASE1	PHASE2	PHASE3	BLA	NEXT MS	FDA/CENSURE		
PREVENTION	Recombinant Botulinum A/B Vaccine							MS C 2017	2022		
	Plague Vaccine							MS C 2015	2019		
	Bioscavenger							MS C 2019	2020		
	Filovirus Vaccine							MS B 2017	2025		
	Ricin Vaccine							MS B TBD	TBD		
	WEVEE Vaccine							MS B 2019	2029		
		MDD	MSA	MSB		MSC (LRIP)					
	PRODUCT		DEV	PRE-CLINICAL	ANALYTICAL	CLINICAL	510K	NEXT MS	FDA CLEARED		
DIAGNOSTICS	Next Generation Diagnostic System – Increment 1							MSC 2016	2016		
	JBAIDS Pre-EUA Diagnostic Kit: Typhus							Pre-EUA	2014		
	JBAIDS Pre-EUA Diagnostic Kit: Burkholderia/Melioidosis							Pre-EUA	2014		
	JBAIDS Food & Water Pathogens							FRP 2015	N/A		
		MDD	MSA	MSB		MSC (LRIP)					
	PRODUCT		IND	PHASE1	PHASE2	PHASE3	NDA	NEXT MS	FDA APPROVAL		
THERAPEUTICS	Advanced Anticonvulsant System							FRP 2016	2016		
	Emerging Infectious Disease (EID) Therapeutics – Flu							MS C 2016	2016		
	Hemorrhagic Fever Virus (HFV) Therapeutic							MS B 2015	2021		
	EID Therapeutics – New Indication							MS C 2021	2021		
	Improved Nerve Agent Treatment System							MS B 2016	2020		

As of Date: 09/09/14

MDD=Material Decision Document

MS=Milestone

LRIP=Low Rate Initial Production

FRP=Full Rate Production

EUA=Emergency Use Authorization

# Products Fielded



LEGEND: PREVENTION DIAGNOSTICS THERAPEUTICS

## NUMBER OF PRODUCTS DELIVERED

CAPABILITY	PRODUCT	FDA LICENSURE	FY02-12	FY13	FY14	TOTAL
PREVENTION	Anthrax Vaccine Adsorbed	2002	13.2 M	.66 M	.39 M	14.3 M
	Smallpox Vaccine	2007	4.5 M	.32 M	.17 M	5.0 M
	Vaccinia Immune Globulin	2005	288	240	0	528
CAPABILITY	PRODUCT	FDA CLEARANCE	FY02-12	FY13	FY14	TOTAL
DIAGNOSTICS	Joint Biological Agent Identification & Diagnostic System (JBAIDS)	2005	340	0	0	340
	JBAIDS Assay Kits	2005-11	22.8 K	2.29 K	945	26.0 K
CAPABILITY	PRODUCT	FDA APPROVAL	FY02-12	FY13	FY14	TOTAL
THERAPEUTICS	Antidote Treatment Nerve Agent Autoinjector (ATNAA)	2002	9.7 M	.28 M	0	9.98 M
	Convulsant Antidote Nerve Agents (CANAA)	1990	5.1 M	.13 M	.07 M	5.3 M
	Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP)	2003	.49 M	.03 M	.01 M	.53 M

As of Date: 09/09/14

# Upcoming Opportunities



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# Opportunities Summary



OPPORTUNITY	CONTRACT TYPE	EST'D MAX VALUE	ISSUE RFP	EST'D AWARD DATE	CONTRACT OFFICE	SMALL BUSINESS SET ASIDE
1. CMDR-B – Multi-drug Resistant MCM	TBD	\$60M	TBD	TBD	ACC-APG Natick	TBD
EID Label Extension	TBD	\$104M	2QFY15	TBD	ACC-APG Natick	FULL
Next Generation Diagnostic System (NGDS) Increment 2	TBD	\$55M	TBD	1QFY16	ACC-APG Natick	TBD
Improved Nerve Agent Treatment System (INATS)	TBD	\$45M	TBD	3QFY16	ACC-APG Natick	TBD
MCS JVAP Non-clinical testing	TBD	TBD	3QFY15	2QFY16	ACC-APG Natick	TBD
MCS JVAP Clinical testing	TBD	TBD	4QFY15	3QFY16	ACC-APG Natick	TBD

# Take Aways



- **MCS develops & delivers FDA-licensed CBRN medical countermeasures**
- **MCS has unique skill sets to support the DoD & U.S. Government**
- **MCS aggressively working to fulfill our mission**
  - Implementing Translational Teaming with S&T
  - Looking creatively at fielding solutions (Interim Fielding Capability)
  - Managing portfolio to mitigate risk
  - Actively pursuing partnering opportunities

# Contact Us



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